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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,122	01/27/2004	Torsten Hoffmann	21558	2112
151	7590	01/12/2006	EXAMINER	
HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110			HABTE, KAH SAY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/766,122	HOFFMANN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Kahsay Habte	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 4,11,12 and 28-30 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 4,11,12 and 28-30 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

1. Claims 4, 11-12 and 28-30 are pending in this application.

### ***Response to Amendment***

2. Applicant's amendment filed 12/01/2005 in response to the previous Office Action (09/02/2005) is acknowledged. Rejection of claims 1-15 under 35 U.S.C. § 112, second paragraph (item 6) has been obviated. Applicant's amendment introduces a new second paragraph issue. Upon further review of this case, it is also deemed necessary to raise new issue that needs further rejection.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 28 and 29 recite "as defined in claim 1", but claim 1 is a cancelled claim. In order to overcome this rejection, claims 28-29 have to depend from claim 4. Alternatively, applicants can overcome the rejection by deleting from claims 28-29 the phrase "as defined in claim 1".

***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 4 and 11-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-4 of allowed copending Application No. 10/196,795. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims 4 and 11-12 and claim 1-4 of allowed copending Application

No. 10/196,795 when formula I of said allowed copending Application No. 10/196,795

has the following substituent:

$$R^1 = F.$$

Claims 4 and 11-12 and claims 1-4 of allowed copending Application No. 10/196,795 are both directed to almost the same invention. The instant claims 4 and 11-12 are drawn to crystalline form of 2-(3,5-bis-trifluoromethyl-phenyl)-N-[6-(1,1-dioxo-1 $\lambda^6$ -thiomorpholin-4-yl)-4-o-tolyl-pyridn-3-yl]-N-methyl-isobutyramide and its pharmaceutical composition and said copending application is drawn to the compound and composition of 2-(3,5-bis-trifluoromethyl-phenyl)-N-[6-(1,1-dioxo-1 $\lambda^6$ -thiomorpholin-4-yl)-4-o-tolyl-pyridn-3-yl]-N-methyl-isobutyramide. The only difference between the two related applications is that the crystalline form of the instant application is described in detailed form, but the compound of claim 1 in the allowed copending application is not. Note that the pharmaceutical composition of the crystalline form is presumed to be the same composition as the pharmaceutical composition of said copending Application recited in claim 4. Even if the crystalline form is different from the compound, it would be the same composition as the one recited in claim 4 of the copending Application once the crystalline form is dissolved e.g. in water. It is presumed that the data recited in the instant claim 4 for the crystalline form is inherently present in compound of claim 1 of said copending Application 10/196,795.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kahsay Habte  
Primary Examiner  
Art Unit 1624

January 6, 2006